REMARKS/ARGUMENTS

The Advisory Action indicates that the amendments presented in the Amendment and Response After Final filed on January 4, 2010 were entered. Thus, the claim listing as above presented reflects amendments to the claims as pending after the Amendment/Response After Final dated January 4, 2010 was entered.

Before entry of this paper, the status of the application is as follows:

- Claims 1-13, 15, 17, 19, 20, 24-29, 31-54, 56, 58, 60, 61, 65-70, 72-79, and 81-84 are pending in the application.
- Claim 83 has been withdrawn from consideration.
- Claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 are rejected in the Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin *et al.* (U.S. Pub. No. 2004/0138712; hereinafter "Tamarkin").
- Claims 11, 12, 15, 17, 18, 31, 32, 35, 36, 38, 52, 53, 56, 58, 59, 72, 73, 76, 77, and 79 are rejected in the Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin and further in view of Ella *et al.* (U.S. Pub. No. 2004/0260209; hereinafter "Ella").
- Claims 33, 34, 37, 74, 75, and 78 are rejected in the Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin, in view of Ella and further in view of Hansjurgens *et al.* (US 5,573,552; hereinafter "Hansjurgens").
- Claims 39, 81, and 82 are rejected in the Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Cosman (U.S. Pat. No. 6,405,572; hereinafter "Cosman").
- Claims 41, 42, and 84 are rejected in the Action under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Lia *et al.* (U.S. Pub. No. 2004/0019286; hereinafter "Lia").

In this paper, claims 1 and 43 have been further amended to incorporate limitations set forth in claims 12 and 53. As such, claims 12 and 53 have been cancelled. No new matter has been introduced.

In view of the amendments above and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections of all the pending claims.

Claim Rejections – 35 U.S.C. § 103(a)

In the Action, claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin. Applicant disagrees and hereby traverses.

Without conceding the validity of the rejection and solely for facilitating the prosecution of the present application, the independent claims (i.e., claims 1 and 43) have been further amended in this paper. Applicant submits that the claims as amended are now inventive over EP 1,219,278 in view of Tamarkin.

In one aspect, the present invention relates to a treatment system for reducing body perimeter at a region of treatment, wherein the system includes "an ultrasound apparatus, for transmitting ultrasound waves to said region of treatment, at an intensity of between 1.5 to 3 W/cm^2; and an electrical stimulation apparatus, for applying electrical stimulation to said region of treatment simultaneously with said transmission of ultrasound waves, wherein said electrical stimulation comprises interferential stimulation" (*see* claim 1 as amended). In another aspect, the present invention relates to a treatment method comprising steps, such as transmitting ultrasound waves at an intensity of between 1.5 to 3 W/cm^2 to the region of treatment, and applying electrical stimulation to the treatment region, wherein the electrical stimulation includes interferential stimulation (*see* claim 43 as amended). Applicant contends that neither of the cited references discloses the specific treatment system or method that is presently recited and claimed.

First of all, Applicant submits that EP 1,219,278 does not disclose a treatment system (e.g., a ultrasonic device) or method as presently claimed. In particular, EP 1,219,278 does not disclose a treatment system or method, in which the ultrasound waves are transmitted at a specific intensity range (that is, between 1.5 and 3 W/cm^2) as required in the present invention. Moreover, EP 1,219,278 does not teach or suggest a system/method, in which electrical stimulation of any form is applied to the treatment region simultaneously with the ultrasound application, let alone a specific form of the electrical stimulation (i.e., "inferential stimulation") required in the present invention. Indeed, the system/method claimed in this application and those disclosed in EP 1,219,278 are patentably distinct. Accordingly, Applicant submits that EP 1,219,278 fails to disclose the presently claimed treatment system/method.

Applicant further submits that Tamarkin does not cure the deficiencies of EP 1,219,278. For example, Tamarkin also fails in teaching or suggesting a treatment system or method, in which the ultrasound waves are transmitted at an intensity of between 1.5 and 3 W/cm^2 (as required in the present invention). Moreover, Applicant notes that Tamarkin does not disclose at all a system/method, which requires the use of ultrasound waves, let alone transmits the ultrasound waves at a specific intensity range (as mandated by the present invention). Moreover, although Tamarkin *arguably* discloses at paragraphs [0031] and [0053] a use of interferential stimulation in a combination treatment, Tamarkin nevertheless fails in teaching or suggesting a **simultaneous application** of *ultrasound* and interferential stimulations to the region of treatment (as recited and claimed in this application), let alone simultaneously applying these stimulations **for the purpose to reduce body perimeter** at the treatment region as intended by the present invention. Thus, Applicant submits that Tamarkin also fails in disclosing the presently claimed treatment system/method.

In view of the foregoing discussions, Applicant submits that the combination of EP 1,219,278 and Tamarkin fails in teaching or disclosing each and every element (e.g., the ultrasound waves are transmitted at an intensity of between 1.5 to 3 W/cm^2) of the presently claimed subject matters.

Moreover, Applicant contends that neither EP 1,219,278 nor Tamarkin provides any motivation or suggestion to a person of ordinary skill in the art to arrive at the presently claimed subject matter. Although EP 1,219,278 discloses an ultrasound device, *nothing* in EP 1,219,278 suggests that the application of ultrasound waves at the specific intensity range (as required in this invention) would produce cavitation effects to an extent necessary for inducing fat dissolution and cracks in the collagen fibers on the treatment region. In absence of such specific teachings, Applicant submits that one skilled in the art would operate ultrasound devices for treating skins and muscles (e.g., cellulite, etc) at an intensity level below 1.5 W/cm^2 under the safety guidelines that are well adopted in the industry.

Moreover, Applicant notes that the apparatus as disclosed in Tamarkin is used for an enhanced delivery of active substances into the skin. Unlike the present invention where cavitation effects are deemed necessary in achieving reduced body perimeter (such as, the breakdown and dissolution of cellulite), a skilled artisan would not be interested in inducing cavitation effects during the operation of a Tamarkin system, as the person would understand

that the cavitation effects are unnecessary in achieving a skin delivery enhancement. Applicant also notes that Tamarkin mainly focuses on using iontophoretic and/or electrical simulation devices to achieve the desired skin delivery of an active substance. It is apparent that ultrasound devices are not of any great interest in Tamarkin. Furthermore, even *assuming* that one is to apply ultrasound waves in a Tamarkin system/method (as asserted in the Action), the operational intensity for ultrasound waves needed to achieve the intended purpose of Tamarkin would still be far below 1.5 W/cm^2 (for the similar safety concerns). Accordingly, Applicant submits that a skilled artisan would not be motivated to reach the presently claimed subject matters by modifying the systems as taught in EP 1,219,278 and/or Tamarkin (at least due to the apparent safety concerns).

In contrast, it is believed by the present inventor that the cavitation effects triggered by the ultrasound waves are crucial for a successful implementation of the treatment system/method presently recited and claimed. Further, the present inventor has discovered unexpectedly that cavitation begins to take effect at an ultrasound intensity of about 1.5 W/cm^2, which is required to induce fat dissolution and cracks in the collagen fibers of the treatment region. The inventor also unexpectedly found that the intended purpose (i.e., reducing body parameter) of the invention can be effectively achieved when the claimed system/method is operated with the operational ultrasound intensity at between 1.5-3 W/cm^2. Thus, Applicant contends the limitation of the operational ultrasound intensity (as recited in the pending claims) is sufficient to differentiate the presently claimed subject matters from the systems disclosed in EP 1,219,278 and/or Tamarkin.

Furthermore, Applicant contends that, when one skilled in the art is presented with the problem which the present inventor was facing (that is, to reduce body perimeter at a treatment region), one would not consider and then rely on Tamarkin for solutions, as Tamarkin is intended for achieving a fundamentally different purpose (that is, enhancing delivery of an active substance into the skin). Likewise, when one skilled in the art is presented with the technical problem which the present inventor has been facing, one would not consider EP 1,219,278 for solving the problem, as EP 1,219,278 merely teaches ultrasound massaging and does not disclose the application of any electrical stimulation (let alone the interferential stimulation) for reducing body perimeter of the treatment region. Accordingly, Applicant submits that one skilled in the art would not be motivated to make a combination of EP 1,219,278 and Tamarkin for the purpose to

arrive at the present invention. Even *assuming* that one is to make such a combination, one would still fail in the attempt as the combination of EP 1,219,278 and Tamarkin does not teach each and every element of the present invention (as above discussed).

Therefore, Applicant submit that claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 are patentable over EP 1,219,278, either alone or in combination with Tamarkin. Thus, the reconsideration and withdrawal of the rejection over EP 1,219,278 in view of Tamarkin is proper and the same is requested.

In the Action, claims 11, 12, 15, 17, 18, 31, 32, 35, 36, 38, 52, 53, 56, 58, 59, 72, 73, 76, 77, and 79 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin and further in view of Ella. Applicant disagrees and hereby traverses.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin is applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin.

Applicant contends that the addition of Ella still fails in rendering the presently claimed subject matter obvious. The Action and the Advisory Action have asserted that Ella teaches an ultrasound apparatus capable of operating at an intensity of between 0.5 to 10 W/cm^2 (*see,* e.g., page 5 of the Action and the Examiner's comments in the Advisory Action). Applicant disagrees. Although Ella discloses an ultrasound apparatus operating at the intensity of 0.5 W/cm^2 when using a continuous waveform, and at an intensity of 120 mW/cm^2 when using a pulsed waveform, Ella nevertheless states that:

> "a safe standard for a continuous waveform ultrasound is about *1 W/cm^2*, for about 15 minutes, for general muscle treatment. For facial treatment, it is about *0.5 W/cm^2*, for about 10 minutes. A safe standard for a pulse waveform is about 240 mW/cm^2. *By comparison*, shattering kidney stones requires about 10 W/cm^2." (*see*, e.g., Ella at paragraphs [0018] and [0020])

Thus, in view of the safety standards as delineated in Ella, one skilled in the art would conclude that ultrasound used for reducing body fat and cellulite should not exceed a level of 1 W/cm^2. A skilled artisan would understand that the statement that "shattering kidney stones requires about 10 W/cm^2" is provided merely as a counterexample, which is used to demonstrate that shattering

kidney stones requires an intensity in an order of magnitude larger than the safety limits associated with other treatments. Thus, one would agree that such a statement neither teaches nor implies that 10 W/cm^2 (or anything above 1 W/cm^2) is a level which is deemed acceptable in the art for cellulite reduction treatment. Still further, nothing in Ella teaches or suggests that its system or method requires an operational intensity in a specific range (that is, between 1.5 to 3 W/cm^2) as required in this invention. Thus, Applicant submits that the addition of Ella still fails in curing the deficiencies of EP 1,219,278 and Tamarkin, at least due to the fact that Ella does not teach or suggest (if not teaches away from) a treatment system or method which requires that the ultrasound waves are transmitted at an intensity of between 1.5 to 3 W/cm^2.

Applicant further contends that Ella does not offer the much-needed motivation or suggestion for a skilled artisan to reach the presently claimed system/method. As above discussed, Ella delineates the safety concerns that will mandate its ultrasound apparatus to be operated at the maximum intensity of 1.0 W/cm^2 for facial and general muscle treatments. As above discussed, Ella does not teach or suggest that its ultrasound device could be operated for general muscle or skin treatments with the ultrasound operational intensity higher than 1.5 M/cm^2. Applicant submits that the intensity level at which the Ella's apparatus is operated falls short to induce sufficient cavitation effects as required for inducing fat dissolution and cracks in the collagen fibers of the treatment region (which is one of the intended purposes for the presently claimed system/method). Indeed, nothing in Ella would motivate a skilled artisan to arrive at the claimed system/method with an operational intensity of the ultrasound waves at 1.5 to 3 W/cm^2.

As such, Applicant submits that claims 11, 12, 15, 17, 18, 31, 32, 35, 36, 38, 52, 53, 56, 58, 59, 72, 73, 76, 77, and 79 are patentable over EP 1,219,278 in view of Tamarkin and further in view of Ella. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

In the Action, claims 33, 34, 37, 74, 75, and 78 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin and Ella, and further in view of Hansjurgens. The rejection is hereby traversed.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin and Ella is also applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin and Ella.

Applicant contends that the addition of Hansjurgens still fails in rendering the presently claimed subject matter obvious. Hansjurgens also fails in teaching or suggesting a treatment system/method with an operational intensity of the ultrasound waves at 1.5 to 3 W/cm^2. As a matter of fact, Hansjurgens does not teach or disclose an ultrasound apparatus at all. Accordingly, Applicant submits that the addition of Hansjurgens fails in curing the deficiencies of EP 1,219,278, Tamarkin and Ella, at least due to the fact that Hansjurgens does not teach or disclose an ultrasound apparatus, let alone operating the said apparatus with an ultrasound intensity of 1.5 to 3 W/cm^2. Moreover, Applicant notes that Hansjurgens does not provide any motivation or suggestion for a skilled artisan to arrive at the presently claimed system/method.

Accordingly, Applicant submits that claims 33, 34, 37, 74, 75, and 78 are patentable over EP 1,219,278, in view of Tamarkin and Ella, and further in view of Hansjurgens. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

In the Action, claims 39, 81, and 82 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Cosman. The rejection is hereby traversed.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin is also applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin.

Applicant contends that the addition of Cosman still fails in rendering the presently claimed subject matter obvious. Specifically, Cosman does not teach or suggest an ultrasound device with an operational intensity of 1.5 to 3 W/cm^2. Rather than using an ultrasound apparatus for reducing body perimeter (as the present invention does), Applicant notes that Cosman only teaches devices for ultrasound imaging. Accordingly, Applicant submits that the addition of Cosman fails in curing the deficiencies of EP 1,219,278 and Tamarkin.

Accordingly, Applicant submits that claims 39, 81, and 82 are patentable over EP 1,219,278, in view of Tamarkin, and further in view of Cosman. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

Furthermore, claims 41, 42, and 84 are rejected in the Action under 35 U.S.C. § 103(a) as allegedly being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Lia. This rejection is now traversed.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin is also applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin.

Applicant contends that the addition of Lia still fails in rendering the presently claimed subject matter obvious. In particular, Lia does not teach or suggest an ultrasound apparatus with an operational intensity of 1.5 to 3 W/cm^2. Nothing in Lia suggests that this specific intensity range for the ultrasound waves is desirable in reducing body parameters. As such, Applicant submits that the combination of EP 1,219,278, Tamarkin and Lia would not render the claimed subject matter obvious, as a combination of these references still fails in teaching or suggesting each and every element of the presently claimed subject matters, and none of these cited references provides any motivation or suggestion to a skilled artisan to arrive at the specific intensity range (i.e., between 1.5 to 3 W/cm^2) of the ultrasound waves that are employed and required in the present invention.

Accordingly, Applicant submits that claims 41, 42, and 84 are patentable over EP 1,219,278, in view of Tamarkin, and further in view of Lia. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

CONCLUSIONS

In view of the foregoing, Applicant submits that all the pending claims of this application are allowable. Applicant respectfully requests entry of this Amendment and Response, reconsideration, and early favorable action by the Examiner. The Examiner is cordially invited to contact Applicant's undersigned representative at the number listed below to discuss any outstanding issues. Applicant thanks the Examiner in advance for this courtesy.

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 04-1105, under the Order No. 64030(303625)

Respectfully submitted,

Date: February 4, 2010
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